DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 3, 2014

Zimmer, Incorporated
Mr. Stephen H. McKelvey, MA, RAC
Senior Project Manager, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K142442
Trade/Device Name: Magna-FX® Cannulated Screw Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, NDG
Dated: August 29, 2014
Received: September 2, 2014

Dear Mr. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142442

Device Name
Magna-FX Cannulated Screw Fixation System

Indications for Use *(Describe)*
The Magna-FX Cannulated Bone Screws are indicated for fractures of:
• The intracapsular hip, femoral condyles, tibial condyles, ankle, acetabulum, pelvis, and other areas where accurate screw placement is required.
• The screw can also be applied to slipped capital femoral epiphysis if image intensification fluoroscopy is used to ascertain the proper position of the screw.

The Mini Magna-FX Cannulated Bone Screws are indicated for:
• Fractures of the medial malleolus, distal tibia, distal radius, calcaneus, talus, patella, and pelvis.
• It can also be used in the reduction of small bone fragments and reduction and fixation with cerclage wire, and the fixation of bone prominences.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen H. McKelvey, MA, RAC Senior Project Manager, Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	September 22, 2014
Trade Name:	*Magna-FX*® Cannulated Screw Fixation System
Common Name:	Screw, Fixation, Bone Washer, Bolt, Nut, Non-Spinal, Metallic
Classification Names and References:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040, HWC) Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030, NDG)
Classification Panel:	Orthopedics/87
Predicate Device(s):	Cannulated Screws and Washers, manufactured by Smith & Nephew, Inc., K111994, cleared October 11, 2011. Synthes 6.5 mm Cannulated Screw, manufactured by Synthes, K021932, cleared September 6, 2002.
Purpose and Device Description:	The *Magna-FX* Cannulated Screw Fixation System consists of a line of cannulated bone screws that are self-reaming and self-tapping and an associated washer. *Magna-FX* screws are designed to provide rigid fixation for various fractures.

Intended Use:

The *Magna-FX* Cannulated Bone Screws are indicated for fractures of: The intracapsular hip, femoral condyles, tibial condyles, ankle, acetabulum, pelvis, and other areas where accurate screw placement is required. The screw can also be applied to slipped capital femoral epiphysis if image intensification fluoroscopy is used to ascertain the proper position of the screw.

The Mini *Magna-FX* Cannulated Bone Screws are indicated for: Fractures of the medial malleolus, distal tibia, distal radius, calcaneus, talus, patella, and pelvis. It can also be used in the reduction of small bone fragments and reduction and fixation with cerclage wire, and the fixation of bone prominences.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- **Shelf Life -** Accelerated aging testing conducted shows that the sterile devices included in this submission have a shelf life of 10 years.

- **Biocompatibility** – Biocompatibility testing of the subject devices was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR 58). All testing passed.

- **Performance Testing** – Testing performed included evaluation of screw torsional properties and axial pull out strength per ASTM F543. The results of non-clinical performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices.

Conclusions: The non-clinical performance data presented in this submission show that the devices are substantially equivalent to the predicate devices.

Clinical Performance and Conclusions: Clinical data and conclusions were not needed for these devices to show substantial equivalence.